



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA-2014-D-1584]

Same Surgical Procedure Exception Questions and Answers Regarding the Scope of the Exception; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comment on draft guidance.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Same Surgical Procedure Exception Questions and Answers Regarding the Scope of the Exception” dated October 2014. The draft guidance document is intended for tissue establishments and healthcare professionals and discusses one of the exceptions for establishments from certain regulatory requirements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at

1-800-835-4709 or 240-402-7800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft document entitled “Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception” dated October 2014. The draft guidance document is intended for use by tissue establishments and healthcare professionals. When finalized, the guidance document will provide our current thinking with respect to the exception set forth in Title 21 of the Code of Federal Regulations 1271.15(b) (21 CFR 1271.15(b)). The draft guidance is presented in question and answer format and includes examples based on inquiries received by the Agency since the final rule, “Human Cells, Tissues, and Cellular and Tissue Based Products; Establishment Registration and Listing” published in the Federal Register of January 19, 2001 (66 FR 5447).

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not

operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910-0543.

## III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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